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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 08/487,283 | 06/07/95 | EVANS | M ALX-152.1CIP |

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HM12/1215

EXAMINER

GAMBEL, P

| | |
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| ART UNIT | PAPER NUMBER |
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1644

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DATE MAILED: 12/15/99

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 8/17/98; 11/4/98; 1/11/99; 3/2/99; 5/20/99; 7/17/99
 This action is FINAL.
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1-23, 25-31 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
 Claim(s) _____ is/are allowed.
 Claim(s) _____ is/are rejected.
 Claim(s) _____ is/are objected to.
 Claim(s) 1-23, 25-31 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
 The drawing(s) filed on _____ is/are objected to by the Examiner.
 The proposed drawing correction, filed on _____ is approved disapproved.
 The specification is objected to by the Examiner.
 The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 All Some* None of the CERTIFIED copies of the priority documents have been
 received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
 Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
 Interview Summary, PTO-413
 Notice of Draftsperson's Patent Drawing Review, PTO-948
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Serial No. 08/487283

Art Unit 1644

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Applicant's amendment, filed 8/17/98 (Paper No. 12), is acknowledged.
Claims 2-4 have been amended.

Applicant's amendment, filed 11/4/98 (Paper No. 13), is acknowledged
Claim 1 has been amended.

Applicant's amendment, filed 1/11/99 (Paper No. 14), is acknowledged.
Claims 18-25 have been added.

Applicant's amendment, filed 3/8/99 (Paper No. 15), is acknowledged
Claim 24 has been canceled.
Claims 20, 21 and 25 have been amended.
Claim 26 has been added.

Applicant's amendment, filed 5/20/99 (Paper No. 16), is acknowledged.
Claim 27 has been added.

Applicant's amendment, filed 7/27/99 (Paper No. 17), is acknowledged
Claim 28 has been added.

Applicant's amendment, filed 10/12/99 (Paper No. 20), is acknowledged.
Claims 29-30 have been added.

Applicant's amendment, filed 12/13/99 (Paper No. 21), is acknowledged
Claims 21 and 28 have been amended.
Claim 31 have been added.

Upon reconsideration and given the number of amended and added claims; the following restriction is set forth.

3. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Serial No. 08/487283

Art Unit 1644

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8, 18-23, 25-27, 29-31; drawn to C5-specific antibodies, and compositions and hybridomas thereof, classified in Class 424, subclass 130.1; Class 530, subclass 387.1, 388.1.

II. Claims 9-12, 28; drawn to C5-specific antibodies encoding nucleic acids, vectors and hosts and methods of producing said antibody, classified in Class 435, subclass 70.21, 252.3, 320.1, 326; Class 536, subclass 23.53.

III. Claim 13, drawn to an isolated oligopeptide, classified in Class 530, subclass 300.

IV. Claim 14, drawn to a method of identifying an anti-C5 antibody by screening with an oligopeptide, classified in Class 435, subclass 7.1.

V. Claim 15, drawn to a method of treatment with C5-specific antibodies, classified in Class 424, subclass 130.1.

VI. Claims 16-17, drawn to methods of refolding single chain antibodies, classified in Class 435, subclass 440.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or diagnostic assays (or detection assays).

6. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as affinity purification procedures or diagnostic assays (or detection assays).

7. Inventions IV and V are different methods of use. These inventions require different ingredients, process steps and endpoints. Therefore they are novel and unobvious in view of each other and are patentably distinct.

8. Inventions I/II/III are different products. Antibodies, nucleic acids, vectors, host cells and peptides are distinct because their structures and modes of action are different. Therefore they are novel and unobvious in view of each other and are patentably distinct.

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Art Unit 1644

9. Inventions I and II/VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the immunoglobulins can be made via a variety of recombinant and biochemical means.

10. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VI is not required for any other group from Groups I-IV and Groups I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.

Patent Examiner

Technology Center 1600

December 14, 1999

Phillip Gambel



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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FROM/ATTORNEY:

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TELEPHONE NUMBER LISTED ABOVE.

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